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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,033	07/23/2003	Matthew Grant Boston	GC538-D1	1263

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EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,033	BOSTON ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/23/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of 09/218,700 now US Patent 6,599,722.

The preliminary amendment filed January 12, 2004 canceling claims 1-58 and adding claims 59-83 has been entered.

Claims 59-83 are pending.

Claim Objections

Claim 59 is objected to because the abbreviation for "glucose dehydrogenase" is mistyped on line 6.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 59 is drawn to a process for the production of 2-keto-D-gluconate (KDG) using *Enterobacteriaceae* cells wherein endogenous genes for both KDG

dehydrogenase and glucose dehydrogenase (GDH) are mutated. The Examiner is unable to locate adequate support in the specification for cells with said double mutations. Thus there is no indication that a process for the production of 2-keto-D-gluconate (KDG) using *Enterobacteriaceae* cells wherein endogenous genes for both KDG dehydrogenase and GDH are mutated were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 59-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 59, with dependent claims 60-72, is drawn to a process for the production of 2-keto-D-gluconate (KDG) using *Enterobacteriaceae* cells wherein endogenous genes for both KDG dehydrogenase and GDH are mutated. Claim 73, with dependent claims 74-83, is drawn to a process for the production of 2-keto-D-gluconate (KDG) using *Enterobacteriaceae* cells selected from the group consisting of *Pantoea*, *Erwinia*, *Enterobacter* and *Gluconobacter* wherein an endogenous KDG dehydrogenase gene is inactivated. Claim 60,dependent from claim 59 limits *Enterobacteriaceae* to *Pantoea*, *Erwinia*, *Enterobacter* and *Gluconobacter.* Claim 61 dependent from claim 60 limits cells to Pantoea. Claim 62 dependent from claim 61 limits cells to *P. citrea*. Similarly, claim

74 dependent from claim 73 limits cells to Pantoea. Claim 75 dependent from claim 74 limits cells to *P. citrea*. Therefore, the claims are drawn to mutated genes from *Enterobacteriaceae.* However, the sequence identity of claimed genes is not defined. Furthermore, while the mutation in KDG dehydrogenase is inactivating, the mutation in GDH is not described by either structure or function.

Enterobacteriaceae is a bacterial Family comprising diverse genera of bacteria. The specification describes it as "bacterial strains having the general characteristics of being gram negative and being facultatively anaerobic" (page 8).

Therefore, claims 59-83 are equivalent to claims that are drawn to genes of an undefined structure from any strain of *Enterobacteriaceae* or genera *Pantoea*, *Erwinia*, *Enterobacter* and *Gluconobacter.*

Thus, the claims recite large highly diverse genera of genes encoding KDG dehydrogenase and GDH.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure

of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification the genus of mutated genes encoding GDH is represented by a mutated GDH, the deletion mutant from *P. citrea.* There is no description of any other GDH mutants. With regard to the genus of mutated genes encoding KDG dehydrogenase, the specification describes the method for producing a *Gluconobacter melanogenus* wherein KDG dehydrogenase gene is deleted (pages 20-21, Example II).

Thus, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding mutated GDH or KDH dehydrogenase from *Enterobacteriaceae* or its genera and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 59-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for genes encoding GDH and KDG dehydrogenase

having known structure and their deletion mutants, does not reasonably provide enablement for the genes having unknown structures and for GDH gene having any mutation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are broader than the enablement provided by the disclosure with regard to the huge number of all possible genomic nucleic sequences and their mutants.

The nature and breadth of the invention of claims 59-83 encompass any *Enterobacteriaceae* (or its genera) nucleic acid sequence encoding the requisite mutated sequence and having an undefined overall structure.

While recombinant hybridization techniques are known, only highly homologous sequences can be identified using a given sequence. The state of the art provides no reasonable expectation of success in obtaining a nucleotide sequence from

Enterobacteriaceae or its genera encoding GDH or KDG dehydrogenase and the result of such screening is unpredictable.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including variant nucleic acid sequences of any structure comprising the specific mutation and having specific activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making a nucleotide sequence from *Enterobacteriaceae* encoding GDH and KDG dehydrogenase and their deletion mutants is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

March 10, 2006